

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147A.27, the Department of Public Health hereby amends Chapter 136, “Trauma Registry,” Iowa Administrative Code.

The rules in Chapter 136 describe the trauma registry procedures and policies. The amendments and associated reasons for those amendments are as follows:

1. The version of the Iowa Trauma Patient Data Dictionary (“data dictionary”) adopted by reference in this rule is updated because the data dictionary was completely revised. The data dictionary had not been updated since 2005. The data dictionary was modified to comply with national standards and to be a support document for the current registry system and transitioned to use of ICD-10 codes.

2. The incorporation by reference of the Iowa EMS Patient Registry Data Dictionary is removed. This reference is being moved to an EMS-specific administrative rule.

3. Reporting requirements for EMS services are removed. These requirements are being moved to an EMS-specific administrative rule.

4. Hospitals are required to submit data electronically and may no longer provide written submissions. Utilization of electronic means to report data has significantly improved since the rule was last updated. These amendments require electronic reporting of data instead of allowing for written reports. There have been updates to national data recommendations through the National Trauma Data Bank (NTDB). These amendments will assist hospitals that elect to report data to the NTDB.

5. Hospitals are required to submit/enter 80 percent of trauma cases to the registry within 60 days of a patient’s discharge and 100 percent of cases within 120 days of a patient’s discharge or next scheduled data upload. This update is consistent with national reporting standards.

6. The offenses and penalties rule is amended to reference rule 641—134.3(147A). This change reduces duplication within the administrative rules.

The Department coordinated with the Trauma System Advisory Council (TSAC), the TSAC data management subcommittee, the Iowa Hospital Association’s Iowa Trauma Coordinators group, and Iowa trauma coordinators and trauma registrars to update the data dictionary. The updates to the data dictionary and associated administrative rule have been occurring over the past year. The TSAC voted to approve the data dictionary and associated administrative rule at the November 1, 2016, meeting.

During the February 10, 2017, Administrative Rules Review Committee meeting, members requested clarification on several aspects of this rule making. The following addresses the identified questions and concerns:

1. A draft 2014 version of the data dictionary was posted to the Department Web site but was not properly labeled as a draft. This draft created confusion for committee members. The 2005 data dictionary and the proposed 2017 data dictionary are now posted in the following location: <https://idph.iowa.gov/BETS/Trauma/data-registry>.

2. Social security number was removed from the registry and data dictionary and is no longer an element for data reporting.

3. Language in 136.2(4)“a” was updated to specify what data are considered confidential.

4. Language in 136.2(6)“c” was updated with a reference to 641—Chapter 178. Chapter 178, “Variances and Waivers of Public Health Administrative Rules,” defines the conditions for and process by which the director may provide a waiver.

5. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) language was reviewed. The language is accurate and consistent with the application of HIPAA for hospitals and the Department. HIPAA allows a covered entity to disclose protected health information to public health authorities for public health activities (Section 164.512). HIPAA defines a public health authority as “an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors

or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate,” (Section 164.501). The Department has such a mandate and, therefore, is a public health authority under HIPAA. The Department, in conjunction with the Iowa Attorney General’s Office, has reviewed its programs and determined that protected health information being received by the Department from covered entities in Iowa is disclosed for public health activities. The disclosure of such information to the Department is, therefore, unaffected by HIPAA and should continue in accordance with past practices.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2902C** on January 18, 2017. No public comments were received. These amendments were modified slightly from those published under Notice as noted in the preamble.

The State Board of Health adopted these amendments on May 10, 2017.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 147A.26.

These amendments will become effective on July 12, 2017.

The following amendments are adopted.

ITEM 1. Adopt the following **new** definition of “Cases” in rule **641—136.1(147A)**:

“Cases” means trauma patients that meet the trauma registry inclusion criteria.

ITEM 2. Amend rule **641—136.1(147A)**, definitions of “ICD9,” “Reportable patient data,” “Trauma care facility,” and “Trauma patient,” as follows:

“~~ICD9~~ ICD10” means International Classification of Diseases, ~~9th~~ 10th Revision, Clinical Modification (ICD-10-CM).

“*Reportable patient data*” means data elements and definitions determined by the department and adopted by reference to be reported to the trauma registry ~~or reported to a trauma care facility~~ on trauma patients meeting the inclusion criteria.

“*Trauma care facility*” means a hospital or emergency care facility which provides trauma care and has been verified by the department as having ~~Resource (Level I)~~ Level I, ~~Regional (Level II)~~ Level II, ~~Area (Level III)~~ Level III or ~~Community (Level IV)~~ Level IV care capabilities and has been issued a certificate of verification pursuant to Iowa Code section 147A.23, subsection 2, paragraph “e.” 147A.23(2) “c.”

“*Trauma patient*” means a victim of an external cause of injury that results in major or minor tissue damage or destruction caused by intentional or unintentional exposure to thermal, mechanical, electrical or chemical energy, or by the absence of heat or oxygen (~~ICD9 Codes E800.0–E999.9~~).

ITEM 3. Rescind the definition of “Service program” in rule **641—136.1(147A)**.

ITEM 4. Amend rule 641—136.2(147A) as follows:

641—136.2(147A) Trauma registry.

136.2(1) Adoption by reference.

a. “Iowa Trauma Patient Data Dictionary” (~~July 2005~~ January 2017) is incorporated by reference for inclusion criteria and reportable patient data to be reported to the trauma registry ~~or reported to a trauma care facility~~. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

b. “Iowa Trauma Patient Data Dictionary” is available through the Iowa Department of Public Health, Bureau of Emergency Medical and Trauma Services (BETS), Lucas State Office Building, Des Moines, Iowa 50319-0075, or the ~~bureau of EMS~~ BETS Web site (www.idph.state.ia.us/ems http://idph.iowa.gov/BETS).

~~c. “Iowa EMS Patient Registry Data Dictionary” (August 2007) is incorporated by reference for inclusion criteria and reportable patient data to be reported to the department. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.~~

~~d. “Iowa EMS Patient Registry Data Dictionary” is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or bureau of EMS Web site (www.idph.state.ia.us/ems).~~

136.2(2) A ~~verified~~ trauma care facility shall report data as follows:

a. ~~Submit~~ Trauma care facilities shall submit reportable patient data identified in 136.2(1) via ~~electronic transfer or in writing~~ electronically to the department. Data shall be submitted in a format approved by the department.

b. ~~Submit reportable patient data identified in 136.2(1) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter~~ Trauma care facilities that enter required trauma data elements identified in 136.2(1) directly into the state registry shall, at a minimum, enter 80 percent of cases within 60 days of a patient's discharge. Within 120 days of a patient's discharge, 100 percent of cases shall be entered into the registry.

c. ~~Submit reportable patient data identified in 136.2(1) to the receiving trauma care facility upon delivery of the injured patient. Data shall be submitted in a format approved by the department~~ Trauma care facilities that submit required trauma data elements identified in 136.2(1) via upload shall, at a minimum, submit 80 percent of cases discharged within the previous 60 days of the first business day of every even-numbered calendar month. Within 120 days of a patient's discharge or next scheduled data upload, 100 percent of cases shall be entered into the registry.

136.2(3) A service program shall:

a. ~~Submit reportable patient data identified in 136.2(1) via electronic transfer. Data shall be submitted in a format approved by the department.~~

b. ~~Submit reportable patient data identified in 136.2(1) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter.~~

c. ~~Submit reportable patient data identified in 136.2(1) to the receiving trauma care facility upon delivery of the injured patient. Data shall be submitted in a format approved by the department.~~

136.2(4) ~~136.2(3)~~ Reportable patient data compilations. The department shall prepare compilations for release or dissemination on ~~all~~ reportable patient data entered into the trauma registry during the reporting period. The compilations shall include, but not be limited to, trends and patient care outcomes for local, regional and statewide evaluations. The compilations shall be made available to all providers submitting reportable patient data to the registry.

136.2(5) ~~136.2(4)~~ Access and release of reportable patient data and information.

a. The data collected by the trauma registry and furnished to the department pursuant to this ~~section~~ rule are confidential records of the condition, diagnosis, care, or treatment of patients or former patients, including outpatients, pursuant to Iowa Code section 22.7. The compilations prepared for release or dissemination from the data collected are not confidential under Iowa Code section ~~22.7, subsection 2~~ 22.7(2). However, information which individually identifies patients shall not be disclosed and state and federal law regarding patient confidentiality shall apply.

b. The department may approve requests for reportable patient data for special studies and analysis provided:

(1) The request has been reviewed and approved by the department with respect to the scientific merit and confidentiality safeguards; and

(2) The department has given administrative approval for the proposal.

(3) The confidentiality of patients and trauma care facilities is protected pursuant to Iowa Code ~~section~~ sections 22.7 and 147A.24.

c. The department may require those requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

136.2(6) ~~136.2(5)~~ Data collection methods. To the extent possible, activities under this ~~section~~ rule shall be coordinated with other health data collection methods.

136.2(7) ~~136.2(6)~~ Quality assurance.

a. For the purpose of ensuring the completeness and quality of reportable patient data, the department or authorized representative may examine all or part of the patient's medical records as necessary to verify or clarify all reportable patient data submitted by a trauma care facility ~~or a service program~~.

b. Review of a patient's medical record by the department shall be scheduled in advance with the trauma care facility ~~or service program~~ and completed in a timely manner.

c. The director, pursuant to rule 641—Chapter 178, may grant a variance from the requirements of rules adopted under this chapter for any hospital, emergency care facility, or service program provided that the variance is related to undue hardships in complying with this chapter or the rules adopted pursuant to this chapter a trauma care facility that meets the requirements of this chapter.

ITEM 5. Amend rule 641—136.3(147A) as follows:

641—136.3(147A) Offenses and penalties. All complaints, offenses and penalties will be addressed pursuant to rule 641—134.3(147A).

~~136.3(1)~~ The department may deny verification as a trauma care facility or deny authorization as a service program or may give a citation and warning, place on probation, suspend, or revoke existing trauma care facility verification or service program authorization if the department finds reason to believe that the facility or service program has not been or will not be operated in compliance with Iowa Code section 147A.26 and these administrative rules. The denial, citation and warning, period of probation, suspension, or revocation shall be effected and may be appealed in accordance with the requirements of Iowa Code section 17A.12.

~~136.3(2)~~ All complaints regarding the operation of a trauma care facility or service program or those purporting to be or operating as the same, shall be reported to the department. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

~~136.3(3)~~ Complaints and the investigative process shall be treated as confidential to the extent they are protected by Iowa Code section 22.7.

~~136.3(4)~~ Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

~~136.3(5)~~ Notice of denial, citation and warning, probation, suspension or revocation shall be effected in accordance with the requirements of Iowa Code section 17A.12. Notice to the alleged violator of denial, citation and warning, probation, suspension, or revocation shall be served by certified mail, return receipt requested, or by personal service.

~~136.3(6)~~ Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice to take action. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If the request is made within the 20-day time period, the notice to take action shall be deemed to be suspended pending the hearing. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. If no request for a hearing is received within the 20-day time period, the department's notice of denial, citation and warning, probation, suspension or revocation shall become the department's final agency action.

~~136.3(7)~~ Upon receipt of a request for hearing, the request shall be forwarded within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

~~136.3(8)~~ The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code.

~~136.3(9)~~ When the administrative law judge makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

~~136.3(10)~~ Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative

law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

136.3(11) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a.* All pleadings, motions, and rules.
- b.* All evidence received or considered and all other submissions by recording or transcript.
- c.* A statement of all matters officially noticed.
- d.* All questions and offers of proof, objections and rulings on them.
- e.* All proposed findings and exceptions.
- f.* The proposed decision and order of the administrative law judge.

136.3(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or personal service.

136.3(13) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

136.3(14) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

136.3(15) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

136.3(16) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, news media or employer.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/7/17.